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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER LEWIS, KIM M	
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/527,421  
Filing Date: November 18, 2005  
Appellant(s): CULLEN ET AL.

Theodore J. Shatynski  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 4/20/10 appealing from the Office action mailed 11/20/09.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 1, 5, 6, 10, 11, 13 and 16-18.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

GB 2,314,842	WATT	1-1998
US 3,032,182	BECHTOLD	5-1962
US 6,409,881	JASCHINSKI	6-2002

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 6, 10, 13, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,314,842 ("Watt et al.") in view of Jaschinski.

As regards claims 1, 10 and 16-18, Watt et al. substantially disclose applicants' claimed invention. More specifically, Watt et al. disclose materials such as freeze-dried sponges that can be used as wound dressings comprising a protein such as collagen complexed with oxidized regenerated cellulose (ORC), wherein the weight ratio of protein collagen and ORC is from 1:99.99 to 99.99:1, which fails within the range of applicants' claimed range (see abstract, page 3, para. 2, and example 1).

Watt et al. fail to disclose that the complex comprises silver from about 0.1 wt. % to about 2 wt. %. Jaschinski, however, teaches that it is known to treat oxidized cellulose with a silver based antibacterial agent in an amount of **0.1 wt. % to 25 wt. %** (col. 24, lines 37-51) in order to confer antibacterial properties to medical products for the inherent purpose of preventing bacterial growth.

In view of Jaschinski, it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat the wound dressing material of Watt et al. with a silver based antibacterial agent, in order to prevent bacterial growth.

With respect to the newly amended range of 0.1 wt. % to 0.3 wt. %, the examiner contends that the claimed range lies inside the disclosed range of 0.1 wt% to 25 wt. %. Applicants should note that it has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990).

Re. claim 5, Jaschinski does not disclose the amount of silver in the products is from about 1 to about 50% by weight. However, it has been held that the optimization of proportions in a prior art device is a design consideration. *In re Reese*, 290 F.2d 839, 129 USPQ 402 (CCPA 1961).

As to claim 6, the disclosed sponge of Jaschinski is inherently a sheet.

As regards claim 13, as can be read from claim 1 above, Watt et al. in view of Jaschinski discloses a wound dressing material comprising a complex of oxidized cellulose with silver, wherein the material comprises from about 0.1% wt% to about 2 wt. % of silver". Neither Watt et al. nor Jaschinski teach a method for treating various ulcers comprising the step of "applying the wound dressing material directly to the surface of the wound. Applicants should first note that it has been held that where the preambular language is part of the definition of the invention, it provides a limitation. *Diversitech Corp. v. Century Steps Inc.*, 850 F. 2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988). Where, however, the preambular language states a purpose or intended use for the invention, it is not a limitation, but merely an indication of a possible use or the environment in which the invention operates. *Loctite Corp. v. Ultraseal Ltd.*, 781 F. 2d 861, 228 USPQ 90 (Fed. Cir. 1985). In the instant case, the preamble is not a limitation. Thus, while Watt et al. and Jaschinski do not disclose that the products are for treating an ulcer, a type of wound, one having ordinary skill in the art would have found it *prima facie* obvious to apply the wound dressing (bandage) to a wound, such as an ulcer, in order to prevent the growth of bacteria due to the antibacterial treatment of the dressing and to also protect and cover the wound.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watt et al. in view of Jaschinski as applied to claim 11 above, and in further in view of U.S. Patent No. 3,032,182 ("Bechtold").

As regards claim 11, Watt et al. fails to teach the wound dressing (bandage) is sterile and packaged in a microorganism-impermeable container. However, Bechtold discloses sterile packaging for use with dressing and various other medical products in order to provide sterilized medical products in a container (package) that prevents the growth of mold or bacteria (col. 3, lines 35-50).

In view of Bechtold, it would have been obvious to one having ordinary skill in the art to provide the modified wound dressing (bandage) of Watt et al. in a package for sterilizing the dressing (bandage) and preventing the growth of bacteria and mold.

#### **(10) Response to Argument**

Appellants argue the following:

1). The Examiner has failed to provide a *prima facie* obviousness rejection as there is no suggestion nor disclosure that an oxidized regenerated cellulose-silver complex first be formed and then incorporated as part of a wound dressing. Appellants also argue that the Examiner's combination does not suggest nor teach why one skilled in the art should first complex the oxidized regenerated cellulose with silver in forming a wound dressing so that the overall wound dressing's silver content (contributed by the ORC-silver complex) is in the range of 0.1 wt. % to 0.3 wt. %;



2). There is no suggestion in the cited documents that maintaining the silver content from the ORC-silver complex in the in the range of 0.1 wt % to 0.3 wt % would achieve the proliferative and anti-inflammatory effects identified by the present inventors. There is no teaching or suggestion in any of the cited documents that this object can be achieved by complexing oxidized regenerated cellulose with silver and then maintaining or reducing the silver content to the range of 0.1 to 0.3 wt. % in the final wound dressing material. Referring back to presented in the instant specification, Appellants argue that the data presented in the present application show that the antimicrobial effect of the silver is lost at the low silver concentration of reference example 7 (i.e., 0.05 wt. % Ag), and that the proliferative effect of the silver is lost at the relatively higher silver concentrations of reference examples 2-5 (i.e., at 0.5 wt. % Ag and higher). Thus, even the preferred range of Jaschinski of 0.1 to 0.5 wt. % silver would yield compositions in which the proliferative effect of silver is lost;

3). Appellants also argue that the proliferative effect of silver at the low concentration range from 0.1 to 0.3 weight % is a completely new discovery, supported by data cited from the specification. Additionally, Appellants argue that a new discovery was made in that the same low concentrations of silver has anti-inflammatory potential and respectfully requests reversal of this rejection; and

4). With respect to claim 11, Appellants finally argue that the Examiner's citing of Bachtold [sic] adds nothing further in view of the Examiner's rejection of Watt and Jaschinski to correct the deficiencies previously identified by Appellant. Therefore, the rejection further in view of Bachtold [sic] is respectfully requested to be reversed.

In response, the examiner first wishes to point out that the claims do not recite that an oxidized regenerated cellulose-silver complex first be formed and then incorporated as part of a wound dressing. Claim 1, for example, recites “[a] wound dressing material comprising a complex of oxidized regenerated cellulose with silver, wherein the amount of silver in the wound dressing material comprises from about 0.1 wt. % to about 0.3 wt. % silver.” Appellants should note that Jaschinski teaches cross-linking the silver to an oxidized cellulose material, which meets the definition of the term “complex” according to Appellants’ definition provided in the specification on page 2. Also, the addition of silver to the sponge of Watt et al. formed from the complex of ORC-collagen, according to the teachings of Jaschinski, renders the claim obvious. Furthermore, Appellants should note that the addition of silver, in the particular range of 0.1 wt. % to 0.5 wt. %, to a wound dressing in order to confer antibacterial properties for the inherent purpose of preventing bacterial growth is taught by Jaschinski. Therefore, the addition of silver to the sponge of Watt et al. in the particular amount of anywhere between 0.1 to 0.5 wt. % would have been *prima facie* obvious in light of the teachings of Jaschinski in order to achieve the desired effect.

In response to Appellants’ argument regarding maintaining silver at 0.1 wt. % to 0.3 wt. % would achieve the proliferative and anti-inflammatory effects not taught by the prior art, Appellants should note the such effects are not presented in the claims of the instant invention, and are therefore irrelevant. Even if such effects were presented in the claims, Appellants should note that since the range of 0.1 wt. % to 0.3 wt. % of silver is taught by Jaschinski, the effects are inherent and necessarily taught by Jaschinski.

In response to Appellants' argument that the use of silver at low concentrations in the range of 0.1 wt. % to 0.3 wt. % has anti-inflammatory potential and respectfully requests reversal of this rejection, the examiner concludes that the new uses/effects are not presented in the claims and are therefore irrelevant.

In response to Appellants' argument that Bechtold adds nothing further in view of the Examiner's rejection of Watt and Jaschinski to correct the deficiencies previously identified by the Appellants, the examiner contends that Appellants' invention is rendered obvious in light of Watts in view of Jaschinski. Furthermore, Bechtold was cited for teaching the known use of a microorganism-impermeable container for packaging a wound dressing to maintain sterility. Thus, the addition of Bechtold to the combination of Watt et al. and Jaschinski cures the deficiency of a lack of a container.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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